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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/271,098	03/18/1999	REY T. CHERN	20023Y	3620

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MERCK AND CO INC
P O BOX 2000
RAHWAY, NJ 070650907

EXAMINER
SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 03/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/271,098	Applicant(s) CHERN ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 13, 2001 has been entered.

Status of the Claims

Claims 1-14 are pending in this application. Claims 1 and 13 are independent claims.

Response to Arguments

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments to the independent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Damani et al US Patent 5,447,725 (Damani).

The instant claims are directed to film coated implant comprising (a) about 1-30% w/v of at least one bioactive substance, (b) about 1-20% w/v of at least a biologically acceptable polymer, and (c) at least one lipophilic solvent or a mixture of at least one hydrophilic solvent and at least one lipophilic solvent, wherein the volume ratio of hydrophilic and lipophilic solvent is from about 65:35 to about 0:100 and/or wherein the lipophilic solvent is present in amount of at least about 16.5% by weight.

Damani discloses fluid gel or paste-like compositions comprising (a) a bioactive substance such as doxycycline or metronidazole respectively in amounts of 15% and 35% (about 30%) w/v, (b) poly (lactide-co-glycolide) copolymers (PLGA) in amounts of 35% or 30% w/v, and (c) lipophilic solvents such as triacetin in amount of 50% or triacetylcitrate in amount of 55% w/v (both solvents are in amounts of at least 16.5% by weight) (see abstract, col 3, lines 58-66; col 4, lines 20-48; col 6, lines 1-10 and lines 30-40). Damani also discloses methods of administering their composition by injecting it through a syringe-like apparatus into the tissue adjacent to tooth surface, gum tissue or root surface (see col 6, lines 29-40 and lines 62-66; col 8, lines 39-67). Thus, Damani

anticipates the components of the instant limitation. Since Damani's composition comprise all components of the instant composition, the compositions of Damani inherently possess similar functional characteristics as those of the instantly claimed compositions such as being effective to form a film coated liquid at an implant site.

Claims 1-4, 7-10, 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Brodbeck et al US Patent 6,130,200 (Broadbeck).

The instant claims are directed to film coated implant and methods of use wherein the implant comprising (a) about 1-30% w/v of at least one bioactive substance, (b) about 1-20% w/v of a PLGA copolymer, and (c) a mixture of hydrophilic and lipophilic solvents, wherein the volume ratio of hydrophilic and lipophilic solvent is from about 65:35 to about 5:95 (claims 1-12); and a film coated implant and method of use thereof wherein the implant comprising (a) about 1-30% w/v of at least one bioactive substance, (b) about 1-20% w/v of at least a biologically acceptable polymer, and (c) at least one lipophilic solvent mixture of at least one hydrophilic solvent and at least one lipophilic solvent, wherein the volume ratio of hydrophilic and lipophilic solvent is from about 65:35 to about 0:100 and/or wherein the lipophilic solvent is present in amount of at least about 16.5% by weight (claims 13-14).

Brodbeck anticipates all the limitations of the instant claims. Broadbeck discloses various gel compositions comprising (a) at least one bioactive agent such as progesterone, hGH or other active agents in amounts of 0.5 to 10% w/v (see col 20, lines 15-17; table 4; col 28, lines 19-61), (b) a biologically acceptable polymer such as PLGA 50:50 (see col 24, lines 45-67; col 25, lines 1-10), and (c) at least one lipophilic

solvent system comprising at least one lipophilic solvent such as triacetin or benzyl benzoate with or without other solvents selected from the group consisting of NMP, glycerin, ethanol, water, glycerol, isotonic saline, and mixtures thereof (see Figures 4-5; col 23, lines 35-45; table 2-3, table 4 formulation N, claims 1, 6, 12, 17).

Applicant's attention is drawn to instant claim 13. Accordingly, the claimed solvent mixture does not require a hydrophilic moiety as the ratio between hydrophilic and lipophilic can be 0:100. Thus, Brodbeck anticipates this claim. Further, the instant hydrophilic and lipophilic solvents are viewed given their broadest reasonable interpretation. Hence, Brodbecks solvent mixtures anticipates the instant hydrophilic, lipophilic solvent mixtures because when the solvents of Brodbecks are mixed together, one would be substantially hydrophilic in relation to the other.

Furthermore, Brodbeck's compositions inherently possess the functional characteristics of the instant claims, because they contain all components that are essential to the functionality of the instant compositions. Finally, Broadbeck discloses administering their compositions by injection into place of interest without surgery, thus Broadbeck anticipates the instant methods of use claims (claims 12 and 14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broadbeck US Patent 6,130,200 in view of Tipton et al US Patent 5,792,496 or Tipton in view of Broadbeck.

Broadbeck teaches that modification of a solvent system wherein the solvent is substantially water immiscible would control the rate of water migration into the polymer implant thus control the delivery of a therapeutic agent of choice (see col 8, lines 61-67; col 10, lines 40-60, see figures 4-5, table 2). Broadbeck fails to teach compositions wherein the concentrations of polymeric moiety are in amount lower than 10% w/v.

Tipton's teachings have been also discussed throughout the prosecution of this application. Specifically Tipton teaches liquid compositions capable of forming a gelatinous matrix when applied in situ (see col 13, lines 60-67; col 14, lines 1-29). Tipton's compositions can not only be used as a dressing but also as a drug delivery implant (see col 3, lines 45-65; col 4, lines 10-18; col 10, lines 25-35). Tipton specifically teaches lower concentrations of his polymeric moiety in amount of about 5% -10 % w/v

(see all examples of Tipton col 13-16). Tipton provides that suitable solvent mixtures and additives can be used to modify the rate of coagulation or solidification of their composition, as well as, their drug release properties (see col 6, lines 49-62; col 10, lines 25-48). However, Tipton fails to specifically teach a solvent mixture wherein the hydrophilic and lipophilic ratio is from about 65:35 to about 5:95.

Both Broadbeck and Tipton teach various gelatinous or liquid drug delivery compositions capable of solidifying in situ, thus their teachings are viewed to be in the same field of endeavor.

Although Brodbeck fails to use lower concentrations of a biologically acceptable polymer in his in situ forming implant compositions, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize such concentrations to a desirable lower level via routine experimentation. Accordingly, absence the showing the criticality, the ordinary skill in the art would have been motivated to modify Brodbecks composition, because as taught by Tipton, he would have had a reasonable expectation to succeed in improving the ease of delivery of such compositions to a site of interest by lowering the viscosity of Brodbeck's composition.

Similarly, Tipton fails to specifically teach the hydrophilic/ lipophilic ratios of the instant solvent system, nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the hydrophilic/lipophlilic components of the solvent mixture of Tipton to the instant ranges by routine experimentation. Accordingly, absence the showing of criticality, the ordinary skill in the art would have been motivated to modify Tipton's composition because as taught by Broadbeck,

preparing a solvent system that is substantially immiscible water would control the rate of water migration into the polymer implant thus improving the sustain delivery of a therapeutic agent of choice.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Beggren et al US Patent 5,783,205 and Dunn et al US Patent 5,990,194 are not used in the instant rejections because they do not appear to add any substantive teachings to the cited art of record.

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, JD can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Shahnam Sharareh, PharmD
Patent Examiner, Art Unit 1617

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March 1, 2002